K111999

APR 17 2012

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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Device Name Trade or Proprietary Name: **Healgen Series Reagent Strips and Analyzers for Urinalysis**

Common or Usual Name: **Urinalysis Test Strips and Analyzers**

Device Format
Healgen 11 Reagent Strips for Urinalysis
Healgen 10 Reagent Strips for Urinalysis
Healgen 4 Reagent Strips for Urinalysis
Healgen 500 Urine Analyzer
Healgen 800 Urine Analyzer

Classification

Product Code	Class	Panel	C.F.R. Section
JIO	CLASS II	HEMATOLOGY	864.6550
JIL	CLASS II	CLINICAL CHEMISTRY	862.1340
CDM	CLASS I	CLINICAL CHEMISTRY	862.1785
JJB	CLASS I	CLINICAL CHEMISTRY	862.1115
JIN	CLASS I	CLINICAL CHEMISTRY	862.1435
JIR	CLASS I	CLINICAL CHEMISTRY	862.1645
JMT	CLASS I	CLINICAL CHEMISTRY	862.1510
LJX	CLASS I	HEMATOLOGY	864.7675
CEN	CLASS I	CLINICAL CHEMISTRY	862.1550
JMA	CLASS I	CLINICAL CHEMISTRY	862.1095
KQO	CLASS I	CLINICAL CHEMISTRY	862.2900
JRE	CLASS I	CLINICAL CHEMISTRY	862.2800

Note: Occult blood test and urinary glucose test are the subjects of this submission.

Predicate Device: URISTK H Series Reagent Strips for Urinalysis and Dirui H-50, H-100, or H-500 Urine Analyzer manufactured by Dirui Industrial Co. Ltd (K040703).

Device Description Healgen Series Reagent strips for Urinalysis and urine analyzers are in vitro diagnostic test devices that use reagents for qualitative and semi-quantitative urinalysis.
The device is composed of several color pads aligned on a strip. Each pad is

employed for testing one assay item by visually or instrumentally reading the color change of the pad and comparing with the corresponding blocks on a color chart.

Healgen Series Reagent Strip provides tests for Glucose, Bilirubin, Ketone, Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Ascorbic Acid and Leukocytes in Urine.

Intended Use/Indications for Use

Healgen Series Reagent Strips for Urinalysis are in vitro diagnostic test devices that use reagents for qualitative and semi-quantitative urinalysis. The strips are for professional use only.

Healgen Series Reagent Strips for Urinalysis are intended for use to detect conditions indicating possible diabetes, metabolic abnormalities, liver diseases, kidney function, and urinary tract infections. Test results can be used along with other diagnostic information to rule out certain disease states and to determine if microscopic analysis is needed.

Test principles

Urobilinogen: this test is based on the Ehrlich reaction in which p-diethylamino benzaldehyde in conjunction with a color enhancer reacts with urobilinogen in a strongly acid medium to produce a pink-red color.

Bilirubin: The direct bilirubin and dichlorobenzene diazonium produce fuchsia azo dyes in a strongly acid medium.

Ketone: The acetoacetate and sodium nitroprusside cause a reaction in the alkaline medium, which produces a violet color.

Blood: Hemoglobin acts as a peroxidase. It can cause peroxidase to release neo-ecotypes oxide [O]. [O] oxidizes the indicator and causes the color change.

Protein: The test is based on the protein-error-of-indicators principle. An ion in the specific pH indicator attracted by cation on the protein molecule makes the indicator further ionized, which changes its color.

Nitrite: Nitrite in the urine and aromatic amino sulphanilamide are diazotized to form a diazonium compound. The diazonium compound reacting with tetrahydro benzo (h) quinolin 3-phenol causes the color change.

Leukocytes: Granulocyte leukocytes in urine contain esterase that catalyzes the hydrolysis of the pyrrole amino acid ester to liberate 3-hydroxy-5-pheny pyrrole. This pyrrole reacting with diazonium forms a purple color.

Glucose: The glucose oxidized by glucose oxidase catalyzes the formation of glucuronic acid and peroxide hydrogen. Peroxide hydrogen releases neo-ecotypes oxide [O] under the function of peroxidase. [O] oxidizes iodide potassium, which causes the color change.

Specific Gravity: Electrolyte (M+X-) in the form of salt in urine reacts with poly methyl vinyl ether and maleic acid (-COOH), which is a weak acid ionic exchanger. The reaction produces hydrogenous ionogen, which reacts with a pH indicator that causes the color change.

pH: This test is based on a double indicator principle that gives a broad range of colors covering the

entire urinary pH range.

Ascorbic Acid: Ascorbic acid, with 1, 2-dihydroxy alkenes, under the alkaline condition, deoxidizes the blue 2, 6-dichloroindophenolate into colorless N- (p-phenol)-2, 6-dichloro-p-amine phenol.

Technological characteristics

Studies were performed with the reference URISTK H Series Reagent Strips for Urinalysis and Urine Analyzer. And substantial equivalence has been demonstrated to the reference method.

Comparison with the predicate:

Differences and Similarities

Item	New Device	Predicate Device
Intended Use	Healgen Series Reagent Strips for Urinalysis are in vitro diagnostic test devices that use reagents for qualitative and semi-quantitative urinalysis. The strips are for professional use only. Healgen Series Reagent Strips for Urinalysis are intended for use to detect conditions indicating possible diabetes, metabolic abnormalities, liver diseases, kidney function, and urinary tract infections. Test results can be used along with other diagnostic information to rule out certain disease states and to determine if microscopic analysis is needed.	This guide instructs the methods, reaction principles and points for attention for the use of URISTK H Series of Reagent Strips. URISTK H Series of Reagent Strips are made for urinalysis both qualitative and semi-quantitative, which are in vitro reagent for diagnostics. The strips are for professional use only. The results on the strips can be read visually and instrumentally. You are required to read the User's Guide before taking use of the strips.
Specimen	Fresh urine	The same
Methodology	Established clinical chemistry methods	The same
Test strip analytes that can be read	Urobilinogen, Bilirubin, Ketone, Blood, Protein, Nitrite, Leukocytes, Glucose, Specific Gravity, pH, and Ascorbic Acid	The same
Strip Incubation Time	Immerse the reagent area of the strip in the urine specimen and take it up quickly and immediately.	The same
Detection	Reflectance Photometry	The same
PC Port	Standard RS232C	The same
Analyzer Operating Conditions	0～40℃;RH < 85%	The same
Wavelength	420nm, 525nm, 560nm, 610nm, 660nm, 950nm	The same
Calibration	Done with a cilibration strip	The same
Strip Operating	Semi-automatic	The same
Available Languages on screen	English	The same
Power Source	AC 220V(±15%),50～60Hz	The same
Line Leakage Current	<0.5 milliamperes in normal condition; <3.5 milliamperes in single fault condition	The same

Memory	1000 test results	The same
Throughput	Healgen 500: 120 test/hour Healgen 800: 500 test/hour	Dirui-50: 60 test/hour Dirui-100: 120 test/hour Dirui-500: 500 test/hour
Dimensions	355mm×300mm×145mm	324mm×327mm×185mm
Weight	4kg	About 5kg
Display Dimensions	Healgen 500 240mm*64mm Healgen 800 240mm*128mm	Dirui-50: 240mm*64mm Dirui-100: 240mm*64mm Dirui-500: 240mm*128mm

Performance

The following are performance characteristics of the Healgen Series Reagent Strips for Urinalysis and Healgen Series Urine Analyzers.

a. Analytical limits (cutoff):

We demonstrated the analytical limits of each assay item as below:

Analyte	Unit	Cutoff
Urobilinogen	mg/dl	0.7
Bilirubin	mg/dl	0.7
Ketone	mg/dl	3.5
Blood	cells/μL	6.5
Protein	mg/dl	7.2
Nitrite	μg/dL	50
Leukocytes	cells /μL	10
Glucose	mg/dl	65
Ascorbic Acid	mg/dl	6.5
pH		5.6
Specific Gravity		1.003

b. Precision (repeatability/reproducibility):

Within-run and within-day precisions were determined at 3 clinical sites by 6 technicians.

In within-run precision testing, 20 replicates were run on each of the 3 levels of urine controls. Each of the 20 replicates was assayed consecutively, using strips obtained from each of 3 lots strips.

In within-day precision testing, the 3 levels were analyzed in duplicate, one a day, for 10 days using strips obtained from 3 lots of strips.

All the 3 formats (Healgen 11, 10 and 4) strips and both of the reading method were used to perform the abovementioned evaluation. For instrumental reading, both Healgen 500 and Healgen 800 were used.

Urinalysis control Level 1 and Level 2 of Bio-Rad and a 3rd control with analyte concentrations around cutoff were used as samples for lower and higher levels.

The 3rd control was obtained by pooling the Bio-Rad controls and spiking with certain kinds of pure analytes to make all the analyte concentrations near the cutoff values.

c. Reportable ranges:

Healgen Series Reagent Strips for Urinalysis are qualitative and semi-quantitative. The strips give results in a small range of concentration of each analyte. All the output values of Healgen Series Reagent Strips are within the laboratory assay ranges. The laboratory assay range and the reportable range of Healgen strips for each analyte are listed in the following table:

Analyte	Unit	Lab Assay Range	Reportable Range
Urobilinogen	mg/dl	0.01-18.75	0.2-8
Bilirubin	mg/dl	0-18.8	0-6
Ketone	mg/dl	0.2-350	0-160
Blood	cells /μL	0-350	0-200
Protein	mg/dl	0.3-5000	0-2000
Nitrite	mg/dl	5.0-2000	Neg-Pos
Leukocytes	cells/μL	0-800	0-500
Glucose	mg/dl	0-5500	0-2000
Specific Gravity		1.000-1.040	1.000-1.030
pH		0-14.0	5.0-8.5
Ascorbic Acid	mg/dl	1-230	0-100

d. Analytical specificity

The interference study was carried out by adding known amounts of potential interfering substances to urine samples and evaluated the test results. 5 test strips from each of 3 lots were used for each interference test, and all the interferents were tested in a one-at-a-time way.

A table of the studied concentrations of the potentially interfering substances that will not have influence on the test results is shown as below:

Potential Interfering Substance	Concentration Not Affecting Test
Albumin	800 mg/dL
Ascorbic Acid	50 mg/dL
Hemoglobin	50 mg/dL
Citric Acid	50 mg/dL
Bilirubin	3.0 mg/dL
Creatine	8 mg/dL
Acetoacetate Acid	1 mmol/L
Ammonium Chloride	189 mg/dL
Calcium Chloride	50 mg/dL
Creatinine	800 mg/dL
Glucose	2000 mg/dL
Glycine	1000 mg/dL
KCL	550 mg/dL
NaCl	2800 mg/dL
Oxalic Acid	70 mg/dL
Sodium Acetate	1200 mg/dL
Sodium Bicarbonate	1500 mg/dL
Sodium Nitrate	0.26 mg/dL
Sodium Nitrite	0.3 mg/dL

Sodium Phosphate	16 mg/dL
Urobilinogen	3.0 mg/dL
Urea	3000 mg/dL
Riboflavin	100 mg/L
Theophylline	100 mg/L
Phenolphthalein	1200 mg/L
pH	9.0
Specific gravity	1.030
Glutathione	200mg/dL
Hypochlorite	10mg/L
Chlorine	1mg/dL
Peroxide	1mg/L
Atropine	300mg/L
Fructose	5000 mg/dL
Lactose	5000 mg/dL
Leucocytes	800 Cell/ μ L
Ketone	200 mg/dL
Blood	300 Cell/ μ L
Mesna	50mg/dL

e. Comparison Studies Using Clinical Specimens

The clinical comparison studies were conducted in 3 sites using the Healgen 11 Reagent Strip for Urinalysis and the predicate devices. Data obtained by visually reading and instrumental reading (Healgen 500 and 800) were collected. The study results indicated that comparable testing data could be obtained by intended users when using the Healgen 11 Reagent Strip for Urinalysis and the legally marketed URISTK H Series Reagent Strips for Urinalysis from Dirui.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993

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Quality Manager
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APR 17 2012

Re: k111999
Trade Name: Healgen Series Reagent Strips and Analyzers for Urinalysis
Regulation Number: 21 CFR 864.6550
Regulation Name: Occult blood test
Regulatory Class: Class II
Product Code: JIO, JIL, CDM, JJB, JIN, JIR, JMT, LJX, CEN,JMA, JRE, KQO
Dated: April 6, 2012
Received: April 9, 2012

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K111999

Device Name: Healgen Series Reagent Strips for Urinalysis

Indications for Use:

The Healgen Series Urine Reagent Strips and Urine Analyzers are in-vitro test systems intended for qualitative and semi-quantitative analysis of Urobilinogen, Bilirubin, Ketone, Blood, Protein, Nitrite, Leucocytes, Glucose, Specific gravity, pH and Ascorbic Acid in urine. The test systems consist of the Healgen Series Reagent Strips (Healgen 10 and Healgen 11) and the Healgen 500 or Healgen 800 Urine Analyzers. The Healgen 10 and 11 strips can be read visually and instrumentally with the Healgen 500 and 800 Analyzers. The Healgen 4 reagent strip can be read visually only. The Healgen Series Urine Reagent Strips and Urine Analyzers are intended for use to detect conditions indicating possible diabetes, metabolic abnormalities, liver diseases, kidney function, and urinary tract infections. Test results can be used along with other diagnostic information to rule out certain disease states and to determine if microscopic analysis is needed.

The Healgen 500 and 800 Urine Analyzers use reflectance photometry to quantitate analyte values from urine samples when using the Healgen 10 and 11 reagent test strips."

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K111999